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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,674	08/19/2003	Suong-Hyu Hyon	1736-000001/REB	5762
27572	7590	05/18/2005	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			BERMAN, SUSAN W	
			ART UNIT	PAPER NUMBER
			1711	
DATE MAILED: 05/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/643,674	HYON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Susan W Berman	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-136 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-136 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/03</u> | 6) <input type="checkbox"/> Other: ____  |

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***Reissue Applications***

This application is objected to under 37 CFR 1.172(a) as the assignee has not established its ownership interest in the patent for which reissue is being requested. An assignee must establish its ownership interest *in order to support the consent to a reissue application required by 37 CFR 1.172(a)*. The submission establishing the ownership interest of the assignee is informal. There is no indication of record that the party who signed the submission is an appropriate party to sign on behalf of the assignee. 37 CFR 3.73(b). Applicant's statement has the party who is signing stating that he is "empowered to sign this certificate". The language the party is "empowered to sign this certificate" instead of "the party is empowered to act on behalf of the assignee" is acceptable; however, the same person who is making the statement also signing the consent form is not acceptable.

A proper submission establishing ownership interest in the patent, pursuant to 37 CFR 1.172(a), is required in response to this action.

A copy of the new claims 12-136 submitted 08/19/2003 should be included with the response to this Office Action because new claims submitted in a reissue application must be underlined in their entirety. See 37 CFR 1.173(d).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-136 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claim

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recitations of “about 1MR”, “about 5 MR”, “about 80<sup>0</sup> C”, “about 50<sup>0</sup> C”, “about 135<sup>0</sup> C to about 155<sup>0</sup> C”, “about 1 hour”, “about 20 hours”. The specification discloses “1.0 MR”, “5.0 MR”, melting point plus “80<sup>0</sup> C”, “50<sup>0</sup> C” less than the melting point, “135<sup>0</sup> C to 155<sup>0</sup> C”, and “1 hour to 20 hours”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-136 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims, as written, fail to specify that the process disclosed by applicant requires irradiating raw UHMWPE followed by heating and compression-deforming the irradiated UHMWPE, followed by cooling and solidifying the irradiated, compression-deformed UHMWPE while keeping the deformed state to obtain the desired product. See column 2, lines 47-55, and column 3, lines 16-20. The order of steps such as heating, cooling, subjecting to pressure, irradiating and processing to form an artificial joint component should be clearly set forth in the claims in order to distinguish the methods recited and products obtained therefrom from the prior art of record. The use of the phrases “not less than about”, “at least about” to define molecular weight, thickness or temperatures or times renders the claims indefinite. If applicant intends to claim a molecular weight of “not less than 5 million”, it should be so stated. If applicant intends to claim a molecular weight of “about 5 million”, it should be so stated. If applicant intends to claim MR or a thickness of “at least ...”, it should be so stated. If applicant intends to claim MR or a thickness, of “about...”, it should be so stated.

#### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40-44, 52-53, 84-88, 97-101, 111-115, 118, 128-132 and 136 are rejected under 35 U.S.C. 102(b) as being anticipated by Sun et al (5,414,049). Sun et al disclose a process for providing an implant from UHMWPE said to usually have a molecular weight from three to six million and up to 10,000,000. Sun et al teach that irradiation in the absence of air produces crosslinking in the polymeric resin (column 2, lines 46-68). Sun et al teach process steps including melting and forming a polymeric resin into an UHMWPE raw material, irradiating a packaged implant (UHMWPE raw material) at a sterilizing dose of about 2.5 Mrad, and heat treating at temperatures from 25<sup>0</sup>C to 140<sup>0</sup>C after irradiation to form crosslinks between free radicals produced upon irradiation. Isothermal treatment at temperatures from 25<sup>0</sup>C to 140<sup>0</sup>C, preferably 130<sup>0</sup>C for 20 hours after melting and forming is taught. See column 1, lines 17-23, column 3, lines 36-45, column 4, lines 20-43, column 5, lines 22-67, column 6, line 42, to column 7, line 8, methods B, C and D and the Examples.

The instant method claims are considered to be anticipated because the claims do not specify the order of "having been crosslinked by irradiation" and "having been heated" or distinguish between compression deformation heating (column 4, lines 4-56 of US '626) and isothermal crystallization heating (column 4, lines 57-67 of US '626). The recitation "having been heated" in the claims, as written, can comprise compression-deforming heating carried out before irradiating the raw article, as disclosed by the equivalent melting and forming step by ram extrusion or compression molding taught by Sun et al in column 4, lines 26-29, and column 5, lines 22-39. Alternatively, "having been heated" in the claims, as

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written, can comprise isothermal crystallization carried out after irradiation, as disclosed by the equivalent heat treatment of the irradiated implant taught by Sun et al in column 4, lines 35-43.

Claims 12-20, 23-36, 38-39, 45-51, 54-62, 66-76, 79-83, 89-95, 102-110, 116-117, 119-125 and 133 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sun et al (5,414,049). Sun et al disclose UHMWPE implants and a process for providing an implant from UHMWPE, said to usually have a molecular weight from three to six million and up to 10,000,000. Sun et al teach that irradiation in the absence of air produces crosslinking in the polymeric resin (column 2, lines 46-68). Sun et al teach process steps including melting and forming a polymeric resin into an UHMWPE raw material, irradiating a packaged implant (UHMWPE raw material) at a sterilizing dose of about 2.5 Mrad, and heat treating at temperatures from 25°C to 140°C after irradiation to form crosslinks between free radicals produced upon irradiation. Isothermal treatment at temperatures from 25°C to 140°C, preferably 130°C for 20 hours for annealing, is taught. See column 1, lines 17-23, column 3, lines 36-45, column 4, lines 20-43, column 5, lines 22-67, column 6, line 42, to column 7, line 8, methods B, C and D and the Examples.

The instant product by process claims 12-20, 23-36, 38-39, 54-62, 66-76, 79-83, 102-110 and 119-125 are considered to be anticipated because Sun et al teach method steps corresponding to the recited methods for preparation of the claimed products and thus the resulting products prepared as taught by Sun et al would be expected to have the same properties as the instantly claimed products. Instant claims 12-16, 31, 32, 54-58, 66-72, 79-83, 84-88, 97-106, and 119-123 are considered to be anticipated wherein the UHMWPE has a molecular weight of about 5 million or more and is in the form of a block or a medical implant, and has been heated, subjected to pressure, cooled and crosslinked by irradiation in any order of required steps. Sun et al specifically disclose irradiating with 2.5 Mrad, which is within the range 1 to 5 MR set forth in the instant claims.

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With respect to product by process claims 14-16, 23, 26-32, 38, 39, 56-58, 69-72, 82, 83, 102-106, 110 and 119-123, Sun et al teach heating to melt and form UHMWPE before irradiation and also teach annealing the UHMWPE after irradiation. The step of melting and forming taught by Sun et al can be conducted by compression molding at the melting temperature. Sun et al also teach heating the irradiated UHMWPE molded article at temperatures from 25 °C to 140 °C to eliminate free radicals by annealing, thus disclosing temperatures within the temperature range set forth in the instant claims. Furthermore, Sun et al teach annealing at a constant temperature, such as at 130° C for 20 hours.

With respect to product by process claims 17-20, 23-25, 33-36, 59-62, 73-76, 107-109, and 124-125 and process claims 45-48, 89-92, 116, 117 and 133, Sun et al teach using compression molding for melting and forming a polymeric resin in a sealed container to provide a polymeric raw material for forming a polymeric medical implant. A method of compression molding would be expected to produce deformation in a direction perpendicular to the plane of compression occurs because it is the compression that causes the deformation. The instantly recited orientation of crystal planes in a direction parallel to the compression plane would be expected to result from the compression deformation method taught by Sun et al because the compression deformation process disclosed would be expected to produce the same results as in the instantly claimed invention, in the absence of evidence to the contrary.

In product by process claims, “once a product appearing to be substantially identical is found and a 35 U.S.C. 102/103 rejection has been made, the burden shifts to the applicant to show an unobvious difference”. MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the “patentability of a product does not depend on its method of production”. *In re Thorpe*, 227 USPQ 964, 96 (Fed. Cir. 1985).

With respect to method claims 49-50 and 93-94 the recited thicknesses of the UHMWPE before and after compression are considered to be properties that would be expected to be obtained by the process steps disclosed by Sun et al, in the absence of evidence to the contrary. With respect to process claims 51 and 95, the cooled article disclosed by Sun et al would be expected to have a melting point

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corresponding to the instantly claimed melting point wherein the starting UHMWPE materials had the same molecular weight and were treated by process steps taught by Sun et al equivalent to the process steps set forth in the instant claims 40, 45, 46 or 84. There is no evidence of record to show that the product obtained has different properties when obtained by the instantly claimed process in comparison with the process taught by Sun et al.

Claims 21, 22, 37, 49, 50, 63, 64, 77, 93 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al (5,414,049) in view of Li et al (5,037,928). See the discussion of Sun et al above. Sun et al disclose melting and forming a polymeric resin into a raw material for forming an implant, such as by compression molding, but do not mention the temperature ranges for melting and forming. Sun et al do not mention the thickness of the block or medical implant to be treated by compression molding or the thickness of the treated block or medical implant. Examples 1-3 and 5 disclose 1 mm thick UHMWPE sheets and Example 4 discloses a 0.5 inch cube, which were used as samples for determining the properties of the products disclosed. Sun et al refer to Li et al '928 for describing a heating and cooling process for preparing UHMWPE (column 3, lines 15-22). Sun et al disclose a heat treatment corresponding to instantly disclosed isothermal recrystallization wherein the temperature range is between about 25 °C and about 140 °C, preferably from 37° C to about 70° C, or the heating is for at least 48 hours at a temperature from 37° C to about 70° C and preferably for 144 hours at 50° C. Sun et al also teach that the higher the temperature the shorter the time period required for crosslinking (column 6, lines 58-61).

Li et al disclose a process for manufacturing UHMWLPE shaped articles comprising heating and cooling in an inert gas atmosphere. Li et al teach heating UHMWLPE under pressure followed by cooling under pressure and cooling while releasing the pressure without allowing remelting, including forming an UHMWLPE article either before heating or after heating and cooling (column 2, line 43, to column 3, line

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20 and column 5, lines 1-5). Li et al also teach that the disclosed process is particularly useful for manufacturing articles from materials having cross-sectional dimensions of at least 1 inch by 1 inch and having temperature gradient problems during the cooling step and for producing articles at least 0.2 inch in thickness (column 3, lines 46-58).

It would have been obvious to one skilled in the art at the time of the invention to employ a block of UHMWPE having a thickness of more than or about 3 cm before compression and to obtain a block having a thickness of more than or about 5 mm after compression in the method disclosed by Sun et al, as taught by Li et al. Sun et al do not limit the thickness of the UHMWPE materials that can be treated as disclosed. Sun et al refer to the teaching of Li et al with regard to melting and forming UHMWPE. Li et al teach that method disclosed is particularly useful for manufacturing articles from materials having cross-sectional dimensions of at least 1 inch by 1 inch and having temperature gradient problems during the cooling step and for producing articles at least 0.2 inch in thickness (column 3, lines 46-58). Thus Li et al provide motivation to employ an UHMWPE article that can produce as article having a dimension of 0.2 inch as its smallest dimension.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan W Berman whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Susan W Berman  
Primary Examiner  
Art Unit 1711

SB  
March 24, 2005